FAO GM Foods Platform Case Study: Canada

July 6, 2015

Canada

Institutional frameworks for GM crops

Novel Foods:
Health Canada, Food Directorate
Novel Foods Section, Pre-market Toxicology Assessment Section, Nutrition Pre-market Assessment Division, Food Contaminants Section

Novel Feeds:
CFIA, Animal Health Directorate
Biotechnology and Microbiology Section, Risk Analysis and Toxicology Section, Feed Evaluation and Nutrition Section

Plants with Novel Traits:
CFIA, Plant Health Science Directorate
Plant Health and Biotechnology Risk Assessment Unit

CFIA, Plant Health and Biosecurity Directorate
Plant Biosafety Office

GM food safety assessment

- Health Canada conducts an assessment based on Codex Alimentarius Commission guidelines (i.e. *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, 2003*)

- Our guidelines, *Guidelines for the Safety Assessment of Novel Foods**, first published in 1994, updated in 2006
  - > Includes guidance on the safety assessment conducted for novel foods derived from genetic modification

*http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php

GM food safety assessment

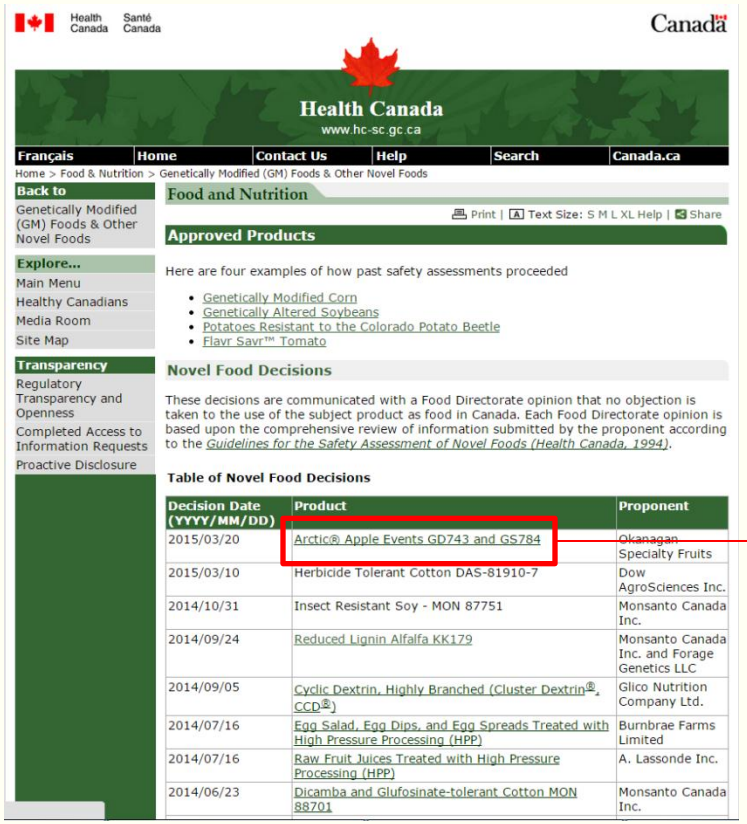
- Food safety assessment consists of:
  - Molecular characterization assessment
  - Toxicological assessment
  - Nutritional assessment
  - Chemical assessment (when applicable)
- Individual assessments assembled into a proposal document (i.e. Food Rulings Proposal) to be reviewed by executive-level committee (i.e. Food Rulings Committee) for final decision (i.e. 'no objection' letter)
- After approval, a Decision Document is drafted for publication on the Health Canada website*

*http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php

No Split Approval policy

- CFIA and HC have a 'No-Split Approval' policy to coordinate approvals of food, feed, and environment simultaneously, avoiding asynchronous approval
- The food, feed and environmental decision making process remain independant but they are coordinated informally.
  - By email
  - By phone

GM food safety assessment



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Approved Products

Here are four examples of how past safety assessments proceeded

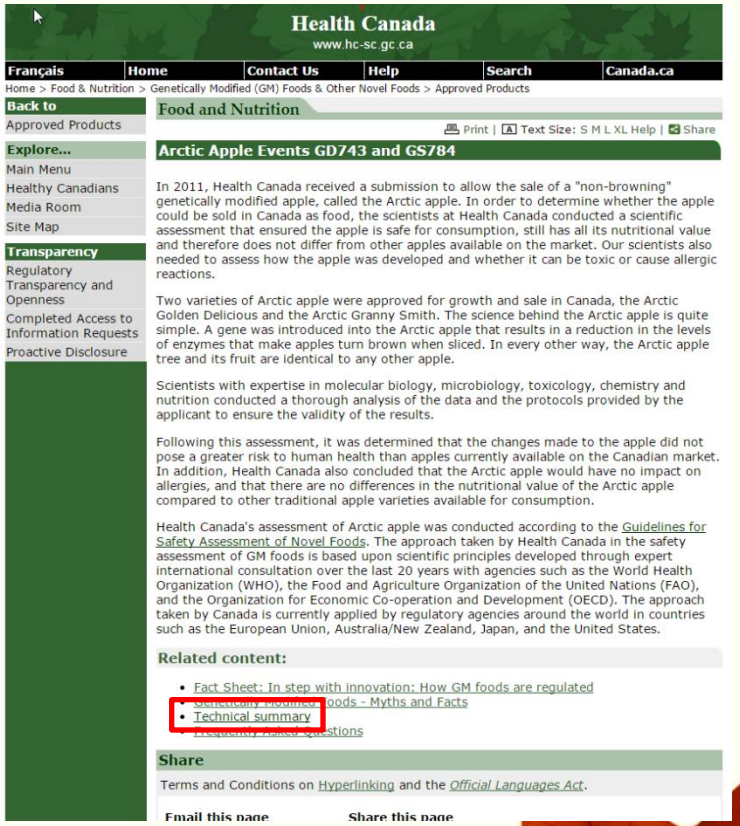
- Genetically Modified Corn
- Genetically Altered Soybeans
- Potatoes Resistant to the Colorado Potato Beetle
- Flavr Savr™ Tomato

Novel Food Decisions

These decisions are communicated with a Food Directorate opinion that no objection is taken to the use of the subject product as food in Canada. Each Food Directorate opinion is based upon the comprehensive review of information submitted by the proponent according to the *Guidelines for the Safety Assessment of Novel Foods (Health Canada, 1994)*.

Table of Novel Food Decisions

Decision Date (YYYY/MM/DD)	Product	Proponent
2015/03/20	Arctic® Apple Events GD743 and GS784	Okanagan Specialty Fruits
2015/03/10	Herbicide Tolerant Cotton DAS-81910-7	Dow AgroSciences Inc.
2014/10/31	Insect Resistant Soy - MON 87751	Monsanto Canada Inc.
2014/09/24	Reduced Lignin Alfalfa KK179	Monsanto Canada Inc. and Forage Genetics LLC
2014/09/05	Cyclic Dextrin, Highly Branched (Cluster Dextrin®, CCD®)	Glico Nutrition Company Ltd.
2014/07/16	Egg Salad, Egg Dips, and Egg Spreads Treated with High Pressure Processing (HPP)	Burnbrae Farms Limited
2014/07/16	Raw Fruit Juices Treated with High Pressure Processing (HPP)	A. Lassonde Inc.
2014/06/23	Dicamba and Glufosinate-tolerant Cotton MON 88701	Monsanto Canada Inc.



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Arctic Apple Events GD743 and GS784

In 2011, Health Canada received a submission to allow the sale of a "non-browning" genetically modified apple, called the Arctic apple. In order to determine whether the apple could be sold in Canada as food, the scientists at Health Canada conducted a scientific assessment that ensured the apple is safe for consumption, still has all its nutritional value and therefore does not differ from other apples available on the market. Our scientists also needed to assess how the apple was developed and whether it can be toxic or cause allergic reactions.

Two varieties of Arctic apple were approved for growth and sale in Canada, the Arctic Golden Delicious and the Arctic Granny Smith. The science behind the Arctic apple is quite simple. A gene was introduced into the Arctic apple that results in a reduction in the levels of enzymes that make apples turn brown when sliced. In every other way, the Arctic apple tree and its fruit are identical to any other apple.

Scientists with expertise in molecular biology, microbiology, toxicology, chemistry and nutrition conducted a thorough analysis of the data and the protocols provided by the applicant to ensure the validity of the results.

Following this assessment, it was determined that the changes made to the apple did not pose a greater risk to human health than apples currently available on the Canadian market. In addition, Health Canada also concluded that the Arctic apple would have no impact on allergies, and that there are no differences in the nutritional value of the Arctic apple compared to other traditional apple varieties available for consumption.

Health Canada's assessment of Arctic apple was conducted according to the Guidelines for Safety Assessment of Novel Foods. The approach taken by Health Canada in the safety assessment of GM foods is based upon scientific principles developed through expert international consultation over the last 20 years with agencies such as the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), and the Organization for Economic Co-operation and Development (OECD). The approach taken by Canada is currently applied by regulatory agencies around the world in countries such as the European Union, Australia/New Zealand, Japan, and the United States.

Related content:

- Fact Sheet: In step with innovation: How GM foods are regulated
- [illegible] foods - Myths and Facts
- Technical summary
- [illegible] Questions

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Canada

Data contribution to the Platform

- Country status in the Platform:
  - 2 Focal Points (Mr. Luc Bourbonnière and Ms. Annie Savoie)
  - Country profile filled out
  - Risk assessment data shared (89 records)
  - Link created

Value of the platform

- Increases transparency, allows countries a venue to place their regulatory decisions online
- For countries facing a Low Level Presence (LLP) issue, the Platform serves as a resource to review safety assessments conducted by other countries (including origin of LLP source)

Possible FAO's roles on the topic

- Agriculture and Agri-Food Canada (AAFC) is developing a Canadian policy model on LLP. Policy model expected to be released soon.
- Objectives: stimulate domestic and international discussions on pragmatic and effective ways to manage LLP in imports.
- Decision on implementation at a later stage. Outstanding technical issues remained to be addressed.
- The Platform will provide valuable intelligence about GM crops approved in other countries and safety assessments performed.

Canada